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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,594	12/13/2005	Amy Newman	1173.1027P	7609
33883 7590 04/16/2008 Birch, Stewart, Kolasch & Birch, LLP 8110 Gatehouse Rd, Suite 500 East P.O. Box 747 Falls Church, VA 22040-0747				
EXAMINER JARRELL, NOBLE E				
ART UNIT		PAPER NUMBER		
1624				
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04/16/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/527,594

Applicant(s)

NEWMAN ET AL.

Examiner

Noble Jarrell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 20-29 is/are pending in the application.
4a) Of the above claim(s) 5, 6, 8-10, 14-16, 22, 24 and 26-28 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-4, 7, 11, 13 and 21 is/are rejected.
7) ☒ Claim(s) 1-4, 11-13, 20-21, 23, 25, 29 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 14 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftperson's Patent Drawing Review (PTO-918)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/14/05/7/3/06
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group VI in the reply filed on 2/27/2008 is acknowledged. The traversal is on the ground(s) that the restriction is improper. This is not found persuasive because different core structures are envisaged by formula I because of variables R_1 , m, A, B, and n. Even though the inventions may be classified similarly (class 544, subclass 358), a search for all the different possibilities of variable R_1 is not considered co-extensive. Separate structural queries are needed for when variable B is a bond or a CH=CH group as well.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 7 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants are not enabled for inhibition of the D₃ receptor with any compound encompassed by the catch-all group, group VI.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in *Wands* states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether

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undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Consideration of the relevant factors sufficient to establish a *prima facie* case for lack of enablement is set forth herein below:

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to treatment of cocaine abuse through inhibition of dopamine D₃ receptors with compound that have a phenyl-piperazine group indirectly connected to an alkene, alkyne, or cyclohexyl group. Thus, the claims taken together with the specification imply that cocaine abuse can be treated with a compound prepared by applicants.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Newman et al. (*Bioorganic and Medicinal Chemistry Letters*, **2003**, 13, 2179-83) teach there are inconsistencies between *in vitro* and *in vivo* models of D₃ receptor function, and further investigation of novel D₃ compound is required (page 2182). In addition, Newman et al. teach compound 23 (page 2180) inhibits D₃ receptors *in vitro* with a K_i of 2.4 plus or minus 1.4 nM. However, this compound does not enable applicants to inhibit the D₃ receptor because it is not "structurally rigid" in the context of this application. In compound 23, an alkane (saturated) chain is connecting the carboxamide and piperazine portions of the molecule. In the context of this application, "structurally rigid" implies that an alkene or alkyne functional group is part of the linking group between the carboxamide and piperazine portions of the molecule. Applicants provide no evidence that these compounds actually work the way in which they are intended to do so.

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(5) The relative skill of those in the art:

One of ordinary skill in the art can perform an assay to determine *in vitro* D₃ receptor inhibition.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification does not provide guidance that any compounds of the elected catch-all group can actually perform the function that is intended.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to claims 7 and 13 and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 11, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Hrib et al. (US 5314923, Issued September 1, 1992, cited in IDS). Hrib et al. teach examples 18-20 (columns 17-18). In each of these compounds, variable R₁ is benzoisothiazole (heteroaryl group), variable A is CH=CH or ethynyl, m and n are each 1, B is a bond, R₂ is OMe, and R₃ is H. Compositions of these compounds are taught from column 10, line 48 to column 11, line 50).

Claim Objections

6. Claims 1-4, 11-13, 20-21, and 25 are objected to because of the following informalities: they contain non-elected subject matter. Appropriate correction is required.

Allowable Subject Matter

7. Claims 23 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: Hrib et al. (same reference as the one used in the 102(b) rejection) teach the closest prior art. The structures disclosed by Hrib et al. fail to anticipate or render obvious compounds where variable R₁ is indole because R₁ is benzoisothiazole in each of these compounds.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is (571) 272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/
Examiner, Art Unit 1624

**/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624**